MAY - 2 2000

Summary Information

510(k) Summary

K001266

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4253

Contact Person: Darlene Phillips

2. **Preparation date**

Date Special 510(k) prepared: April 19, 2000

3. **Device name**

Trade or Proprietary Name:	VITROS Immunodiagnostic Products Folate Reagent Pack 1/2 VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3 VITROS Immunodiagnostic Products Red Cell Folate Pack VITROS Immunodiagnostic Products Folate Calibrators
Common Name:	Folate assay
Classification Name:	test for the *in vitro* quantitative measurement of folate in human serum, plasma (heparin) and whole blood (red cell folate).

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4. Predicate device

The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Red Cell Folate Pack and VITROS Immunodiagnostic Products Folate Calibrators (modified device) are substantially equivalent to the VITROS Immunodiagnostic Products Folate Reagent Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Red Cell Folate Pack and VITROS Immunodiagnostic Products Folate Calibrators, (original device), (K984166, January 6, 1999).

5. Device description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products Folate Reagent Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Red Cell Folate Pack and VITROS Immunodiagnostic Products Folate Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Folate assay).

2. The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

   The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

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6. Device intended use

The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2 and the VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3 – for the *in vitro* quantitative measurement of folate in human serum and plasma (heparin) and whole blood (red cell folate) to aid in the differential diagnosis of anemia.

The VITROS Immunodiagnostic Products Folate Calibrators – for *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of folate in human serum, plasma (heparin) and whole blood.

The VITROS Immunodiagnostic Products Red Cell Folate Pack – for whole blood sample preparation, to allow the *in vitro* quantitative measurement of red cell folate using the VITROS Immunodiagnostic System.

7. Comparison to predicate device

The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Red Cell Folate Pack and VITROS Immunodiagnostic Products Folate Calibrators (modified device) are substantially equivalent to the VITROS Immunodiagnostic Products Folate Reagent Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Red Cell Folate Pack and VITROS Immunodiagnostic Products Folate Calibrators (original device) which were cleared by the FDA (K984166) for IVD use.

There is no change in the fundamental scientific technology of the modified device.

Table 1 lists the characteristics of the assays performed using the VITROS Folate assay (modified device) and the VITROS Folate assay (original device).

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Table 1 List of Assay Characteristics Comparison to Predicate Device

Device Characteristic	VITROS Folate assay (modified device)	VITROS Folate assay (original device)
Calibrator Storage	Store at ≤ –18°C.	Store at 2-8°C.
Calibration range	0 – 20 ng/mL	0 - 20 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Binding protein	Folate binding protein, purified from bovine milk	Folate binding protein, purified from bovine milk
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample type	Serum, plasma (heparin) and whole blood.	Serum, plasma (heparin) and whole blood.
Sample volume	53 µL	53 µL
Incubation time and temperature	64 minutes at 37°C	64 minutes at 37°C

8. Conclusion

The data presented in the pre-market notification demonstrate that the performance of the VITROS Folate assay using modified Folate Calibrators is substantially equivalent to the cleared predicate device.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Folate assay using modified Folate Calibrators is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Ms. Darlene J. Phillips
Regulatory Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626

Re: K001266
Trade Name: VITROS Immunodiagnostic Products Folate Reagent Pack 1/2
VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3
VITROS Immunodiagnostic Products Folate Calibrators
VITROS Immunodiagnostic Products Red Cell Folate Pack
Regulatory Class: II
Product Code: CGN, JIS
Dated: April 19, 2000
Received: April 20, 2000

Dear Ms. Phillips:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K001166

Device Name:

1. VITROS Immunodiagnostic Products Folate Reagent Pack 1/2
2. VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3
3. VITROS Immunodiagnostic Products Folate Calibrators
4. VITROS Immunodiagnostic Products Red Cell Folate Pack

Indications for Use:

1. & 2. The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2 and the VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3 – for the *in vitro* quantitative measurement of folate in human serum and plasma (heparin) and whole blood (red cell folate) to aid in the differential diagnosis of anemia.

3. The VITROS Immunodiagnostic Products Folate Calibrators – for *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of folate in human serum, plasma (heparin) and whole blood.

4. The VITROS Immunodiagnostic Products Red Cell Folate Pack – for whole blood sample preparation, to allow the *in vitro* quantitative measurement of red cell folate using the VITROS Immunodiagnostic System.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001166

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)